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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,180	02/26/2004	Catherine C. Turkel	17679 (BOT)	9912

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EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,180	TURKEL ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *21-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) ___ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/12/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 12, 2005 has been entered.

2. Newly submitted claims 21-28 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Newly submitted claims 21-28 are drawn to a method for preventing an acute pain medication overuse disorder comprising a step of local administration of a botulinum toxin concurrently with an acute pain medication to a patient with a headache thereby preventing the acute pain medication overuse disorder. The claims currently under examination are drawn to a method of treating an acute pain medication overuse disorder comprising a step of local administration of botulinum toxin. The examined claims and the newly submitted claims are directed to two distinct methods that use different reagents and have different goals. Since, Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-

28 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Rejection Maintained

3. The rejection under 35 U.S.C. 103(a) as unpatentable over Katsarava et al in view of Aoki et al is maintained for claims 1-20 the reasons set forth on pages 3-5, paragraph 3 of the Final Office Action.

The rejection was on the grounds that Katsarava et al teach a study of 98 patients that have medication overuse headaches (see Title and the Abstract). Katsarava et al teach that 71% of the patients had migraine headaches, 14% of the patients had tension-type headaches and 15% had chronic headaches (page 1682). Katsarava et al teach that the study was designed so that patient would withdraw from taking "headache medications"(page 1682). Katsarava et al teach that medication withdrawal relapse rate for patients was 38%. Katsarava et al teach that two predictors for relapse found during the study were type of primary headache and type of overused headache medication (page 1683). Katsarava et al teach that the relapse was lower for patients that suffered from migraine headaches than patients that suffered from tension-type headaches or a combination of migraine and tension-type headaches (see the Abstract).

Katsarava et al do not teach the use of botulinum toxin to treat headaches and headache related symptoms.

Aoki et al teach a method of treating a tension headache by intramuscular or subcutaneous administration of botulinum toxin to the head or neck location of a patient, thereby relieving tension headache pain (columns 9-10). Aoki et al teach that botulinum toxins types A-G can be used in the invention (see the Abstract). Aoki et al teach that dosages of botulinum toxin used in the invention range from about 0.01 units to about 1000 units (column 4). Aoki et al teach that botulinum toxin can be administered to the facial muscles of a patient (column 1, Example 1).

It would be *prima facie* obvious at the time the invention was made to use botulinum toxin to treat patients that have medication overuse disorder because Katsarava et al teach that medication overuse disorder is associated with patients that have migraine and tension-type headaches and medication withdrawal relapse is more likely to occur in patients that have tension-type headaches. Aoki teach that botulinum toxin can be used to treat patient that suffer from tension-type headaches. One would be motivated to administer botulinum toxin to a patient suffering from medication overuse disorder and chronic headaches since botulinum toxin has been shown to treat patients with headaches, especially tension-type headaches. It would be expected

barring evidence to the contrary, that the administration of botulinum toxin to a patient suffering from medication overuse disorder would be effective in preventing the patient against medication withdrawal relapse.

Applicant urges that the claims have been amended to limit the scope of the claims to treating an acute pain medication overuse disorder caused by overuse of acute pain medications. Applicant urges that Katsarava et al and Aoki et al do not teach or suggest a method of treating pain medication overuse disorder caused by overuse of acute pain medication by administering botulinum to a patient thereby treating the pain medication overuse disorder.

Applicant's arguments filed July 12, 2005 have been fully considered but they are not persuasive. It is the position of the Examiner that the combination of references teach the claimed invention. Katsarava et al teach that patients evaluated in the study with medication overuse headache were patients that have overused acute pain medication such as analgesics, ergots and triptans. (page 1682). Katsarava et al teach a study of 98 patients that have medication overuse headaches. Katsarava et al do not teach the use of botulinum toxin to treat headaches and headache related symptoms. Aoki et al teach a method of treating a tension headache by intramuscular or subcutaneous administration of botulinum toxin to the head or neck location of a patient, thereby relieving tension headache pain. One would be motivated to administer botulinum toxin as taught by Aoki et al to a patient suffering from medication overuse disorder as taught by Katsarava et al because Aoki et al teach that botulinum toxin has been shown to treat chronic headaches, especially tension-type headaches. One of ordinary skill in the art could reasonably concluded that administering botulinum toxin to

a patient suffering from medication overuse would be effective in treating medication overuse relapse. Thus, if headaches are lessened, then medication overuse relapse would lessen, particularly in patients overusing triptan medications. Therefore, it would have been obvious at the time the invention was made to combine the prior art references to arrive at the claimed invention. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention.

New Ground of Rejection

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim 1-20 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 11/039, 506 filed January 18, 2005. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets claims (claims 1-20 of this application and claims 1-17 of copending Application No. 11/039, 506) are drawn to a method of treating medication overuse patients by administering botulinum toxin to the patients. It should be noted that "triptan medication overuse patients" would be a species of the genus "medication overuse patients". Therefore, the scope of the claims 1-20 of this application would encompass the scope of claims 1-17 of copending Application No. 11/039, 506.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Status of Claims

5. No claims allowed.

Conclusion

6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
September 28, 2005

L. R. F. Smith
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